Tab 5 OCT 5 2007

510(k) Summary (Revised)

Submitters Name:	Tiller MIND BODY, Inc.
Contact:	Jeri C. Tiller
Address:	10911 West Ave San Antonio, Texas 78213 (210) 308-8888 Office (210) 349-5679 Fax
Date Prepared:	April 12, 2007
Trade Name:	LIBBE Colonic Nozzle
Common Name:	LIBBE Colonic Nozzle
Classification Name:	Colonic Irrigation System

The legally marketed device to which we are claiming equivalence [(807.92(a) (3)]:

The Libbe Colonic Nozzle is equivalent to the Libbe Rectal Tube (K962259), which was granted approval on August 29, 1996 (Tab 5 – Attachment A.)

Description of the Device:

The LIBBE Colonic Nozzle device is a plastic, non-sterile, single use product for use as an accessory with lower bowel evacuation systems or enema kits. The Device/Nozzle is intended to be inserted two to three inches into the rectum for instilling water into the colon region.

The LIBBE Colonic Nozzle is designed as a one-piece, injection molded, medical grade plastic accessory. The nozzle has an open tip with a slight bulb shape that has two small holes in its wall. The proximal end of the nozzle has a barbed fitting for attachment to plastic tubing from the colonic irrigation, or enema, system.

Indications:

The Libbe Colonic Nozzle is to be used as the Device/Nozzle inserted into the rectum when used with the LIBBE Lower Bowel Evacuation System. The Device/Nozzle is intended for colon cleansing when medically indicated, such as before radiological or endoscopic examination.

Technical Characteristics:

Technological characteristics of our LIBBE Colonic Nozzle compared to the predicate device, the Libbe Rectal Tube (K962259), are the same except for the length, material used, and the addition of a bulb shape at the tip. The bulb tip of our new nozzle has two holes in its wall and is open. The predicate device has a smooth tip that is open and has two small holes. The predicate device is narrower than the LIBBE Colonic Nozzle and is rigid plastic, while our Libbe Rectal nozzle is semi-rigid plastic.

In addition, the proximal end of the LIBBE Colonic Nozzle has a barbed fitting for attachment to plastic tubing from the LIBBE colonic system. The predicate device is a continuous, straight tube with a smooth wall at the equipment connection point.

Biocompatibility:

The LIBBE Colonic Nozzle meets biocompatibility requirements as specified in FDA Guidance G95-1, and has been tested in accordance with ISO 10993. (See Letter of Authorization from Kraton Polymers LLC, Tab 15.)

Tab 5 - Attachment A

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 29 1996

Ms. Jeri C. Tiller
President
Tiller MIND BODY, Inc.
2204 N.W. Loop 410, #2C
San Antonio, Texas 78230-5352

Re: K962259
LIBBE Rectal Tube
Dated: June 6, 1996
Received: June 12, 1996
Regulatory class: II
21 CFR §876.5220/Product code: 78 KPL

Dear Ms. Tiller:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4616. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

William L Yin

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Tiller MIND BODY, Inc.
c/o Mr. Harold L. Jones
Consultant
Quality Partners Consulting
42 East Whisters Bend Circle
THE WOODLANDS TX 77384

OCT 5 ' 2007

Re: K071057
Trade/Device Name: LIBBE Colonic Nozzle
Regulation Number: 21 CFR §876.5220
Regulation Name: Colonic irrigation system
Regulatory Class: II
Product Code: KPL
Dated: July 24, 2007
Received: July 27, 2007

Dear Mr. Jones:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1796, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Tab 4

Indications for Use Statement (Revised)

510(k) Number (if Known): **K071057**

Device Name: **Libbe Colonic Nozzle**

Indications for Use: "The Libbe Colonic Nozzle is to be used as the Device/Nozzle inserted into the rectum when used with the LIBBE Lower Bowel Evacuation System. The Device/Nozzle is intended for colon cleansing when medically indicated, such as before radiological or endoscopic examination."

Prescription Use ___X___ AND/OR Over-The-Counter Use ____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

(Division Sign-Off)
Division of Reproductive, Abdominal, and
Radiological Devices
510(k) Number K071057